

U.S. patent application Ser. No. 10/664,366
Response to Office Action dated November 7, 2006
Amendment dated April 8, 2007

AMENDMENTS TO THE CLAIMS:

Please replace the previous listing of claims with the following listing of claims.

Listing of Claims:

1. (Currently Amended) ~~[[An]]~~ The air introduction device ~~for use in anastomotic leak testing, comprising: a single member, elastomeric body, defining an interior space and having a of~~ claim 35, wherein

said proximal portion is adapted to be inserted into an anus of a person such that said proximal portion causes the anus to constrict around said proximal portion and thereby seal said proximal portion against the anal wall, ~~a distal portion adapted to mate with an inflation pump to enable air to be directed from the inflation pump into and through said body and~~

said body further including an expanded portion having a larger size than said proximal portion and interposed between said proximal portion and said distal portion,

said expanded portion being adapted to engage with an anal opening to limit insertion of said proximal portion into the anus and seal said body against the anal opening, ~~said proximal portion having a longitudinal axis, said expanded portion extending radially outward from said proximal portion around the entire periphery of said proximal portion.~~

2. (Currently Amended) The air introduction device of claim ~~[[1]]~~ 35, wherein said proximal portion includes a rounded or tapered tip having a smaller cross-section than said proximal portion to facilitate insertion of said proximal portion into the anus.

3. (Previously Presented) The air introduction device of claim 1, wherein said expanded portion includes a circular

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portion having a largest diameter of said expanded portion and which extends beyond an outer periphery of said proximal portion around the entire periphery of said proximal portion, a first truncated conical surface tapering from said largest diameter circular portion to said proximal portion and a second truncated conical surface tapering from said largest diameter circular portion to said distal portion.

4. (Currently Amended) The air introduction device of claim [[1]] 35, wherein said distal portion defines a lumen adapted to mate with a connector of the inflation pump device.

5. (Withdrawn) The air introduction device of claim 1, wherein said body is substantially tubular, said proximal portion being defined by a wall having an outer diameter of about 1.062 inches, said expanded portion being defined by a wall having a maximum outer diameter of about 1.75 inches and said distal portion being defined by a wall having an inner diameter of about 0.375 inches.

6. (Currently Amended) The air introduction device of claim 1, wherein said distal portion has first and second arms connected to said expanded portion of said body, said first arm defining a first lumen and an opening at an end opposite said expanded portion communicating with said first lumen, said first lumen being adapted to mate with a connector of the inflation pump device, said second arm defining a second lumen and an opening at an end opposite said expanded portion communicating with said second lumen.

7. (Previously Presented) The air introduction device of claim 6, wherein said second arm includes a constriction.

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8. (Previously Presented) The air introduction device of claim 6, wherein said proximal portion and said expanded portion have a common central axis and said second arm of said distal portion has a central axis parallel to said common central axis of said proximal portion and said expanded portion.

9. (Currently Amended) The air introduction device of claim ~~[[1]]~~ 35, wherein said distal portion has first and second arms, said first arm defining a first lumen adapted to mate with a connector of the inflation pump device and, said second arm defining a second lumen and an opening to an exterior of said body communicating with said second lumen, further said regulating means comprising a pressure relief valve arranged in connection with said second lumen for releasing air to the exterior of said body when a specific air pressure in the rectum is reached.

10. (Previously Presented) The air introduction device of claim 9, further comprising signal means for providing a signal when air is released via said valve.

11. (Previously Presented) The air introduction device of claim 10, wherein said signal means comprise a component arranged in connection with said second arm and arranged to produce an audible signal when air is released via said valve.

12. (Currently Amended) ~~The An~~ air introduction device of ~~claim 1 for testing an anastomosis for leaks, wherein said distal portion has first and second arms, said first arm defining a first lumen adapted to mate with a connector of the inflation~~

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~~pump, said second arm defining a second lumen, further~~
comprising:

a body having a proximal portion adapted to be inserted into a patient's gastrointestinal tract and a distal portion adapted to mate with an air inflation device to enable air flow through said body into the gastrointestinal tract when said proximal portion is inserted into the patient's gastrointestinal tract,
and

a component signal indicator device arranged at least partially in connection with said second arm body and arranged to produce an audible generate a signal when a specific air pressure in the patient's gastrointestinal tract is reached within the rectum.

13. (Currently Amended) An air introduction device for ~~use in anastomotic leak testing~~ an anastomosis for leaks, comprising
a ~~single member~~ body defining an interior space and
comprising

insertion and sealing means for enabling insertion of a proximal portion of said body into an anus of a person such that the anus constricts around said proximal portion and thereby seals said body against the anal wall,

~~insertion limiting means for limiting insertion of said proximal portion of said body into the anus and occluding an opening of the anus, said insertion limiting means comprising an expanded portion of said body including a circular portion having a largest diameter of said expanded portion and which extends radially outward from a longitudinal axis of said proximal portion beyond an outer periphery of said proximal portion around the entire periphery of said proximal portion, and~~

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coupling means for enabling coupling of said body to an air inflation pump device such that air is directable from the inflation pump through said coupling means device into said interior space in said body; and

regulating means arranged in connection with said body for regulating air pressure in the patient's bowel, said regulating means being arranged to release air from the patient's bowel when the air pressure in the patient's bowel exceeds a predetermined pressure.

14. (Previously Presented) The air introduction device of claim 18, wherein said first and second arms of said distal portion are connected to said expanded portion of said body and each of said first and second arms includes a lumen and an opening at an end opposite the expanded portion.

15. (Withdrawn-Currently Amended) The air introduction device of claim [[14]] 49, wherein said body is substantially tubular and said insertion-limiting means comprise an expanded portion of said body arranged behind said proximal portion and having a larger diameter than said proximal portion, said expanded portion being adapted to engage with the anal opening to limit insertion of said proximal portion into the anus and seal said body against the anal opening.

16. (Previously Presented) The air introduction device of claim 14, wherein said proximal portion includes a rounded tip having a smaller cross-section than said proximal portion to facilitate insertion of said proximal portion into the anus.

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17. (Currently Amended) The air introduction device of claim 13, wherein said coupling means comprise a first lumen arranged on a distal portion of said body and adapted to mate with a connector of the inflation ~~pump~~ device.

18. (Previously Presented) The air introduction device of claim 17, wherein said distal portion has first and second arms, said first arm defining said first lumen, said second arm defining a second lumen.

19. (Previously Presented) The air introduction device of claim 18, further comprising a pressure relief valve arranged in said second lumen for releasing air when a specific air pressure in the rectum is reached.

20. (Previously Presented) The air introduction device of claim 19, further comprising signal means for providing a signal when air is released via said valve.

21. (Previously Presented) The air introduction device of claim 20, wherein said signal means comprise a component arranged in connection with said second arm and arranged to produce an audible signal when air is released via said valve.

22. (Previously Presented) The air introduction device of claim 18, further comprising a component arranged in connection with said second arm and arranged to produce an audible signal when a specific air pressure is reached within the rectum.

23-32. (Canceled)

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33. (Withdrawn-Currently Amended) An ~~anastomotic~~
anastomosis leak tester, comprising:

an inflation pump having a compressible central portion, a pair of valves on opposite sides of said central portion and arranged to provide a uni-directional flow of air through said central portion upon intermittent compressing of said central portion; and a connector; and

the air introduction device of claim ~~[[1]]~~ 35 said distal portion being arranged to mate with said connector of said inflation pump.

34. (Currently Amended) The air introduction device of claim ~~[[1]]~~ 12, ~~further comprising means for generating wherein~~
said signal indicator device is arranged to generate an audible indication when ~~[[a]]~~ the specific air pressure in the patient's bowel gastrointestinal tract is reached.

35. (Currently Amended) ~~The~~ An air introduction device of ~~claim 1 for testing an anastomosis for leaks,~~ further comprising:

a body having a proximal portion adapted to be inserted into a patient's gastrointestinal tract and a distal portion adapted to mate with an air inflation device to enable air flow through said body into the gastrointestinal tract when said proximal portion is inserted into the patient's gastrointestinal tract, and

regulating means arranged in connection with said body for regulating air pressure in the patient's bowel gastrointestinal tract, said regulating means being arranged to release air from the patient's gastrointestinal tract when the air pressure in the patient's gastrointestinal tract exceeds a predetermined pressure.

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36. (Currently Amended) The air introduction device of claim 35, wherein said regulating means are arranged to release air from the patient's ~~bowel~~ gastrointestinal tract when a specific air pressure in the patient's ~~bowel~~ gastrointestinal tract is reached.

37. (Currently Amended) The air introduction device of claim 35, wherein said regulating means comprise a pressure relief valve having an inlet communicating with ~~said an~~ an interior space of said body communicating with the patient's ~~bowel~~ gastrointestinal tract and arranged to allow air to be released from the patient's ~~bowel~~ gastrointestinal tract when a specific air pressure in the patient's ~~bowel~~ gastrointestinal tract is reached.

38. (Previously Presented) The air introduction device of claim 37, further comprising means for generating an audible indication when air is released via said pressure relief valve.

39. (Currently Amended) The air introduction device of claim [[35]] 1, wherein said distal portion comprises two arms each of which communicates with said expanded portion, a first one of said arms being matable with the inflation ~~pump~~ device, said regulating means comprising a pressure relief valve arranged in connection with a second one of said arms such that an inlet of said pressure relief valve communicates with ~~said an~~ an interior space of said body and an outlet of said pressure relief valve communicates with the ambient atmosphere.

40. (Currently Amended) The air introduction device of claim 35, wherein said regulating means comprise a pressure

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relief valve structured and arranged such that when the air pressure in the ~~bowel~~ gastrointestinal tract is above a specific air pressure, said pressure relief valve opens a conduit for air flow from the ~~bowel~~ gastrointestinal tract to the ambient atmosphere.

41. (Currently Amended) The air introduction device of claim ~~[[1]]~~ 35, ~~further comprising a mechanism for releasing wherein said regulating means are arranged to release~~ air from the patient's ~~bowel~~ gastrointestinal tract when a specific air pressure in the patient's ~~bowel~~ gastrointestinal tract is reached and ~~for generating to generate~~ an audible indication when air is being released.

42. (Currently Amended) The air introduction device of claim 41, wherein said distal portion comprises two arms ~~each of which communicates with said expanded portion~~, a first one of said arms being receivable of the inflation pump device, said ~~mechanism~~ regulating means being arranged in connection with a second one of said arms.

43. (Currently Amended) The air introduction device of claim 41, wherein said ~~mechanism comprises~~ regulating means ~~comprise~~ a component having upper and lower flaps.

44. (Previously Presented) The air introduction device of claim 1, wherein said expanded portion expands outward from said proximal portion uniformly around the entire periphery of said proximal portion.

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45. (Currently Amended) The air introduction device of claim [[1]] 35, wherein said body is monolithic.

46. (New) The air introduction device of claim 12, wherein said body is made of an elastomeric material.

47. (New) The air introduction device of claim 12, wherein said body is a single member.

48. (New) The air introduction device of claim 13, wherein said body is made of an elastomeric material.

49. (New) The air introduction device of claim 13, wherein said body is a single member.

50. (New) The air introduction device of claim 13, wherein said regulating means are arranged at least partially in said body.

51. (New) The air introduction device of claim 13, wherein said body further comprises insertion-limiting means for limiting insertion of said proximal portion of said body into the anus and occluding an opening of the anus.

52. (New) The air introduction device of claim 35, wherein said body is made of an elastomeric material.

53. (New) The air introduction device of claim 35, wherein said body is a single member.

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54. (New) The air introduction device of claim 35,
wherein said regulating means are arranged at least partially in
said body.